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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LEE, YUN HAENG NMN

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 04/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/754,493

Applicant(s)

HACKER ET AL.

Examiner

Yun H. Lee

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/6/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims are rejected under 35 U.S.C. 103(a) as being unpatentable over Drongeten (US Pat. No. 6,224,549).

Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding claim 1, Drongeten discloses a monitoring system comprising a stimulator (50) and inherently comprising a power source which powers the system including the stimulator. Without a power source, the device would not be operable.

The system of Drongeten is inherently capable of delivering a complete cycle of biphasic electrical stimulation for application to anatomical tissue as a first group of a selected number of positive or negative pulses followed by a second group of a selected number of pulses of reverse polarity to said pulses of said first group. It is well known that conventional electrical stimulators are capable of biphasic electrical stimulation by cathodal stimulation and anodal stimulation.

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Drongeten does not explicitly disclose automatically following the first group by the second group. It would have been a simple matter of well-known electromechanical configuration to enable the system of Drongeten to automatically follow the first group by the second group. Further, this automation would be advantageous since it would reduce the number of manual steps that need to be taken. Thus, it would have been obvious for one of ordinary skill in the art at the time of invention to configure the system of Drongeten to automatically follow the first group by the second group since it would reduce the number of manual steps that need to be taken.

The intended use recited in the preamble (i.e., intraoperative) was considered, but deemed insufficient to saliently distinguish over the art of record in the absence of any structural recitation in the claim body limiting the device to such an arena.

Regarding claims 2, 3, 5, 7 and 9, the system of Drongeten is clearly capable of performing the claimed intended uses, as discussed above and further below.

Regarding claim 4, Drongeten teaches of enabling selection of pulse current amplitude (col. 16 lines 56-57). Drongeten is silent as to what ranges of current amplitude are available. Clearly those of ordinary skill in the art wishing to design the system of Drongeten would have seen the optimal range of selectable current amplitudes to be a matter of obvious design. Criteria such as patient safety and varying stimulus thresholds for different patients and different applications would necessarily weigh in the decision as to the range of selectable current amplitudes chosen. The courts have long

determined that the optimization of ranges within prior art conditions through routine experimentation is obvious (see MPEP 2144.05).

Regarding claims 6, 8 and 10, similar arguments as in claim 4 apply. Drongeten teaches of enabling selection of number of pulses, duration of pulses and inter-pulse intervals (see col. 16 lines 34-35 and 56-57). Further, configuration of stimulation parameters such as amplitude, repetitions, duration, frequency, rate, polarity, morphology, etc. is notoriously old and well known in the electrical stimulation art. The exact selectable parameters would be seen as a matter of obvious design choice.

Regarding claim 11, a power source and a power console can be considered the same thing. See above discussion of claim 1.

Regarding claim 12, Drongeten discloses a monitoring system as discussed above in claim 1 and further comprising an activator (34). The activator of Drongeten is inherently capable of being actuated by the user to input commands to the system to complete an activation that starts delivery of said first group of pulses, said activation being effective to deliver said complete cycle of biphasic electrical stimulation.

Regarding claim 13, the activator of Drongeten is inherently actuatable to complete said activation in a two-step procedure performed by the user such as 1) pressing a button; and 2) releasing the button.

Regarding claim 14, the activator of Drongeten comprises a hand switch (any key on the keyboard).

Regarding claim 15, Drongeten further discloses a screen (38) and a control option on said touch screen (numerous control options can be seen in figs. 4-16) as part of the activator. Drongeten does not explicitly disclose the screen to be a touch screen. The examiner takes Official Notice that it is well known to use touch screens for simplicity instead of using a mouse coupled to a screen. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to include a touch screen in the system of Drongeten instead of the monitor (38) and the mouse (36) for simplicity.

Regarding claim 16, the limitations are met by the above discussion of claim 12.

Regarding claim 17, Drongeten discloses a monitoring system as disclosed above and further comprising a patient interface unit (30) being connectible to monitoring electrodes (col. 5 line 26). The monitoring electrodes can be placed on a patient to detect responses to stimulation for display on the display screen (col. 5 lines 23-32). Regarding the claimed first and second form of electrical stimulation, the system of Drongeten is inherently capable of a multitude of forms of electrical stimulation depending on the configuration of the stimulation parameters (see above discussion of claims 4, 6, 8 and 10).

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The patient interface unit is also connectible to stimulating probes (col. 5 lines 46-48).

Although Drongeten does not expressly disclose the stimulating probes being monopolar or bipolar, those of ordinary skill in the art would have seen the provision of both types of stimulating probes for the type of system disclosed by Drongeten to be blatantly obvious given their ubiquitous nature in electrical stimulators.

Regarding the patient interface unit delivering the first form of electrical stimulation up to a current amplitude of about 30 mA and the stimulator delivering the second form of electrical stimulation up to a current amplitude of about 200 mA, see the above discussion of claims 4, 6, 8 and 10.

Regarding the stimulator delivering the second form of electrical stimulation in the positive phase and the negative phase, see the above discussion of claim 1.

Regarding claim 18, the system of Drongeten is capable of performing the claimed intended uses. See the above discussion of claims 4, 6, 8 and 10.

Regarding claim 19, the limitations are met by the above discussions of claims 1 and 3.

Regarding claim 20, see the above discussion of claims 4, 6, 8 and 10.

Regarding claim 21, Drongeten discloses a plurality of displays (figs. 4-16, 19 and 20) including control options for selecting the pulse width, the current amplitude, the rate, the number of pulses, the delay and the mode (col. 16 lines 35-57).

Regarding claim 22, the limitations are met by the above discussion of claim 12.

Regarding claim 23, Drongeten discloses a plurality of monitoring channels (col. 5 line 24) each connectible to a pair of monitoring electrodes (74).

Regarding claims 24-26, the limitations are met by the above discussion of claim 17.

Regarding claim 27, see col. 11 lines 14-26.

Regarding claim 28, see col. 11 line 57 – col. 12 line 2.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yun H. Lee whose telephone number is (571) 272-2847. The examiner can normally be reached on M-Th 9-7.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Robert Pezzato
Supervisory Patent Examiner
Art Unit 3766

yhI